

Remarks

The Application has been reviewed in light of the Final Official Action of July 13, 2006. Claims 14 and 18 are amended. Claim 26 is new. Claims 14-18, 20, 21, 23 and 26 are pending in the Application.

No new matter is introduced by the amendments. The amendments correspond to matter disclosed in figures 8-11A and the descriptions associated with these figures.

The Examiner rejected claims 14-17, 20 and 21 under 35 U.S.C. 103(a) as being unpatentable over Luscombe et al. (US 5,683,418). The Examiner rejected claims 18 and 23 under 35 U.S.C. 103(a) as being unpatentable over Sklar et al. (WO 98/23229) in view of Luscombe. Applicant requests that the Examiner reconsider the rejection of claim 14 and its dependent claims in light of the fact that the claim as amended requires that "one of the first surface and second surface is adapted to engage a bone tunnel wall and the other surface is adapted to engage a ligament; wherein the body comprises a thickness between the first surface and the second surface that is dimensioned such that when one surface engages the bone tunnel wall and the other surface simultaneously engages the ligament, the ligament is forced against a bone tunnel wall; and a shim hole extending from the arc-shaped surface to the second surface, the body being otherwise devoid of any further opening." Applicant requests that the Examiner reconsider the rejection of claim 18 in light of the fact that the claim as amended requires that "the body comprises a thickness between the first surface and the second surface that is dimensioned such that when the first surface engages a first ligament and the second surface simultaneously engages a

second ligament, both the first and second ligaments are forced against bone tunnel walls; and a shim hole extending from the first arc-shaped surface to the second arc-shaped surface, the body being otherwise devoid of any further opening."

In order for the claimed invention to be obvious over the prior art, there must be some suggestion or motivation in the cited references to modify or combine the references in accordance with the claimed invention. See, MPEP §2143; *In re Mills*, 916 F.2d 680, 682, 16 USPQ2d 1430, 1432 (Fed. Cir. 1990). Further, the prior art references must teach or suggest all of the claim limitations. See MPEP §2143.

The Examiner references Luscombe with respect to claim 14 and its dependent claims. Luscombe discloses two configurations for a suture anchor in figures 1-6 and figures 13-17 that enables soft tissue such as a ligament to be attached to a bone. The configuration in figures 1-6 discloses a suture anchor 1 that has a substantially cylindrical cross-section and a suture opening 5. (col. 4 l. 31-39). Luscombe disclose that the "diameter of the suture anchor is sized smaller than the bore hole or opening in the bone receiving the suture anchor." (col. 4 l. 34-36). Luscombe also discloses that the suture anchor is installed by passing a suture 10 through the opening 5, wedging one end of suture anchor 1 with corner 4 into the bore hole and engaging the opposing end 3 with the opposite wall. (col. 4-5 l. 61-8). Luscombe discloses that this method "securely implants the anchor within the bone material permitting attachment of soft tissue or other materials through the use of suture 10." (col. 5 l. 10-13). The figures also disclose that the ligament is secured to the bone in a region that is exterior to the bore hole. The configuration in

figures 13-17 discloses a suture anchor 100 with a wedge shaped body 101 and a suture opening 102. (col. 5 l. 38-42). These figures show that the wedge shaped body has two parallel surfaces that extend from the wide end to the narrow end and the suture opening passes through these surfaces. The two other surfaces that extend between these two ends are abutment wall 103 and plow wall 104. (col. 5 l. 43-54). Luscombe discloses that these walls 103, 104 have radii that improve the contact with the bore hole. Id. Figs. 19-20 disclose that suture anchor 100 is installed by threading a suture 111 through suture opening 102, digging edge 105 into the bone and engaging abutment wall 103 firmly against the bore hole. (col. 7 l. 14-30). As above, with the suture anchor secured within the bore hole, a soft tissue can be secured to the bone using suture 111 in a region exterior to the bore hole. All embodiments of Luscombe disclose that the thickness of the suture anchor only needs to be sufficient for the suture anchor to fit within the bore hole; that the suture anchor is secured within the bore hole by wedging the ends of the anchor within the hole; that the suture opening within the anchor enables a ligament to be secured to the bone and is not utilized to secure or fix the position of the anchor within the hole; and that ends other than the surfaces through which the suture opening passes are adapted to engage the bore hole. As a result, Luscombe does not disclose that “one of the first surface and second surface is adapted to engage a bone tunnel wall and the other surface is adapted to engage a ligament; wherein the body comprises a thickness between the first surface and the second surface that is dimensioned such that when one surface engages the bone tunnel wall and the other surface simultaneously engages the ligament,

the ligament is forced against a bone tunnel wall; and a shim hole extending from the arc-shaped surface to the second surface, the body being otherwise devoid of any further opening.”

Applicant submits that there is no motivation to modify the structural elements in Luscombe in accordance with claim 14 and its dependent claims because the structural elements interact with a bore hole in a manner distinct from the structural elements of these claims. Luscombe is directed to a device that tethers a ligament to an anchor and secures the ligament to a bone in a region exterior to the bore hole. Luscombe discloses shaping the ends of the anchor such that they are able to wedge the anchor within the bore hole. The only requirement that Luscombe places on the thickness of the anchor between the surfaces through which the suture hole passes is that the thickness be small enough for the anchor to be placed in the bore hole. Such a structural limitation on thickness is made without any need to take into account the ability to force the ligament against the wall of the bore hole. Further, neither of these surfaces engage the wall of the bore hole or the ligament. Since Luscombe disposes the ligament outside of the bore hole and only places a requirement that the thickness of the anchor be such that it fits within the hole, one skilled in the art would not be motivated to modify Luscombe such that “one of the first surface and second surface is adapted to engage a bone tunnel wall and the other surface is adapted to engage a ligament; wherein the body comprises a thickness between the first surface and the second surface that is dimensioned such that when one surface engages the bone tunnel wall and the other surface simultaneously engages the ligament,

the ligament is forced against a bone tunnel wall; and a shim hole extending from the arc-shaped surface to the second surface, the body being otherwise devoid of any further opening.”

Based on the foregoing, Applicant submits that claim 14 and its dependent claims are not obvious in view of Luscombe.

The Examiner references the embodiment of figures 7-9 in Sklar with respect to the majority of the limitations of claim 18 and states that it would have been obvious to combine the suture hole in Luscombe with the device in Sklar. (page 3). Sklar discloses a graft ligament engagement means that comprises plate means 48 which is movable transversely within the bone opening. (page 11-12). Fig. 7 shows a single plate having, on a first surface, one or more concavities for nesting one or more graft ligaments respectively. (page 12). A locking means 32 that can be an expansion plug 46 or a rocker arm type of cam member 34 that is adapted to impinge a second major surface 52 of plate means 48. (page 12). Sklar discloses that the locking means 32 bears against plate 54, moves plate 54 to engage ligament 28, and secures ligament 28 against sidewall 38 of opening 24. (page 12). As shown in Fig 8, Sklar discloses screwing the plug 46 threaded partly into the bone and engaging plate such that the ligament is compacted against the wall of the opening. (See p.12-13.). If the ligament needs to be further secured within the opening, Sklar teaches incorporating gripper ribs 58 on the surface that engages ligament 28. (page 13). It is clear from Sklar that these ribs further the ability of the plate to compress and secure the ligament. Thus, Sklar discloses a mechanism to

secure a ligament against an inner wall of a bone opening; that secures the ligament utilizing compression; that if the ligament needs to be further secured, elements that promote compression and frictional resistance are incorporated; that utilizes a plate that has one surface adapted to engage a ligament and an opposing surface that is adapted to engage a locking means; that the plate has a thickness that is dimension such that the ligament, the locking means and the plate may be simultaneous disposed within the hole; and that does not utilize a suture or incorporate a suture hole. As a result, Sklar does not disclose that “one of the first surface and second surface is adapted to engage a bone tunnel wall and the other surface is adapted to engage a ligament; wherein the body comprises a thickness between the first surface and the second surface that is dimensioned such that when one surface engages the bone tunnel wall and the other surface simultaneously engages the ligament, the ligament is forced against a bone tunnel wall; and a shim hole extending from the arc-shaped surface to the second surface, the body being otherwise devoid of any further opening.”

Applicant submits that there is no motivation to modify Sklar in accordance with the claim 18 because Sklar teaches away a body that “comprises a thickness between the first surface and the second surface that is dimensioned such that when the first surface engages a first ligament and the second surface simultaneously engages a second ligament, both the first and second ligaments are forced against bone tunnel walls.” Sklar discloses a device that relies on compression to secure the ligament to the interior wall of the bone opening. To achieve this compression Sklar discloses that it is necessary to

dispose the locking means against one surface of the plate and the ligament against the opposing surface. This indicates that one skilled in the art would not be motivated to dispose the plate between two ligaments. Further, Sklar teaches that the thickness of the plate must accommodate both the locking means and the ligament. Thus, one skilled in the art would not be motivated to alter the thickness of the plate such that "when the first surface engages a first ligament and the second surface simultaneously engages a second ligament, both the first and second ligaments are forced against bone tunnel walls." As a result, one skilled in the art would not be motivated to modify Sklar in accordance with claim 18.

Further, Applicant submits that one skilled in the art would not be motivated to combine the suture hole in Luscombe with the plate in Sklar. Luscombe is directed to a device that tethers a ligament to an anchor and secures the ligament to a bone in a region exterior to the bore hole. Sklar is directed to a device that compresses a ligament against an interior wall of a bone opening. Neither reference indicates that the elements of devices that secure ligaments to different regions of a bone can be combined or equally applied to one another. Since the references are different in their objectives as to where on a bone to secure a ligament and are directed to different methods of securing a ligament to a bone (tethering v. compression). One skilled in the art would not be motivated to combine the references.

The Examiner suggests that the motivation to combine the references is "to be able to guide a suture through the opening to aid in positioning and securing the shim in

position in view of Luscombe et al." (page 3). However such an objective and functionality of a suture opening and a suture is not disclosed in Luscombe. Luscombe only discloses that the suture opening and the suture enable the ligament to be tethered to the anchor and secured to a portion of the bone exterior to the bore hole. The anchor in Luscombe is positioned within the bore hole utilizing shafts 6 or 107. The anchor in Luscombe is secured within the bore hole by wedging its sides against the interior walls of the bore hole. Thus, if one skilled in the art sought to improve the ability to position and secure the shim in Sklar in position, based on the teachings in Luscombe one skilled in the art would utilize a shaft and attempt to wedge the ends of the plate against the interior walls of the bone opening. One skilled in the art would not modify the shim to incorporate "a shim hole extending from the first arc-shaped surface to the second arc-shaped surface, the body being otherwise devoid of any further opening."

Further, one skilled in the art would not look to Luscombe in order to improve the ability to secure the shim in Sklar within the bone opening. Luscombe discloses an anchor that is secured by wedging the ends of the anchor within the bore hole. Sklar teaches securing the shim within the bone opening utilizing a locking means that is adjacent to a plate. The locking means and the plate are sized such that the bone opening can still accommodate a ligament and urge the ligament against the opening wall. If one skilled in the art were to apply the teachings in Luscombe on how to secure the anchor to Sklar the shim would be wedged against the interior walls of the bone opening. This would likely preclude the ability of the ligament to be simultaneously disposed within the opening with

the shim. Further, even if a ligament could be disposed within the opening with a wedged shim, wedging the shim in the manner disclosed by Luscombe would likely damage the ligament and defeat the purpose of Sklar. For this reason, Applicant submits that one skilled in the art would not be motivated to combine the references.

Still further, even if the references were to be combined such a combination would not necessarily result in a suture opening passing through the plate in Sklar. If one skilled in the art sought to achieve the Examiner's suggested motivation, a suture opening could just as easily be disposed within locking means 32 and equally achieve the proposed objective. For this additional reason, Applicant submits that one skilled in the art would not be motivated to combine the references in accordance with the claimed invention.

Finally, Applicant submits that Applicant's disclosure cannot be relied upon to establish the motivation to combine the references or the expectation of success in combining Sklar with Luscombe. In responding to Applicant's argument that there would not be any motivation to combine the references, the Examiner states "[i]t is noted that the applicant's specification describes the claimed invention taking the form of a shim both without and with a shim hole for the same intended purpose." (page 4). However, the "teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)." MPEP §2142. As a result, Applicant submits that any motivation to apply a suture hole to the plate in Sklar cannot be based on Applicant's disclosure.

In view of the foregoing amendments and remarks, it is respectfully submitted that all of the claims currently pending in the application are now in condition for allowance. Reconsideration and notice to that effect is earnestly requested.

Respectfully submitted,

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